

FIG. 1

Study Setup

- Clinical Study Definition
 - Describes Sponsors & Investigators
 - Declares Subject Attributes to Capture
 - Associates Specific Lab Procedures with a Clinical Study
 - Defines Genotype Results to Report

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture Associates Specific
- Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

Results to Report

Study Protocols	
Study Number 632-001	Sponsor A Co., John Doe, Ph.D.
Sample test PST	Sponsor Representative John Doe, Ph.D.
Sponsor Study No. 1-98-005	
Study No. 632-001	
Investigator: John Doe, Ph.D.	
Sponsor Protocol Title: Pharmacokinetic Evaluation of Dros(R) (oxybutylin chloride) and IR oxybutylin Administered Alone and in the Presence of Ketoconazole	
PPG# Protocol Title: Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "G", "D", "E", "H", and "T" alleles	
Procedures: DNA Isolation, 3 mL whole blood, Purgene Kit SpectroMax DNA quantitation CYP2C9*3 CYP2C9*2 Ver. 7	Subject Attributes: Subject Number Gender Birthdate Ethnicity
Final Storage Tube Range (*)	Cascade Accession Number
Barcode Length:	Define Results
Created DNALIMS 10/4/99 12:02	Modified DNALIMS 10/5/99 14:32

Fig. 2

- Accessioning
- Clinical Sample Registration
- Provides Validation Checks for Accession & Tube ID's
 - Accommodates Multiple Sample Tubes
 - Enforces Controlled Subject Attribute Terms
 - Supports Sample Workflow

Accessioning

Study No.	Accession No.	Sponsor Sample Tube ID	Sample Tube ID	Received Date	Location
632-001	A100123	BA10112	PS22156	09-OCT-1999	
632-001	A100124	BA10113	PS22157	09-OCT-1999	
632-001	A100125	BA10114	PS22158	09-OCT-1999	
632-001	A100126	BA10115	PS22159	09-OCT-1999	

PPGx Study No: 632-001

Sponsor: A Co. (John Doe, Ph.D.)

Accession No: A100126

Date Received: 09-Oct-1999

Sample Type: Fresh Whole Blood

Print

Save As a Worksheet

Query

Tube 1

Tube 2 (*)

Tube 3 (*)

Tube 4 (*)

Sponsor Sample Tube ID: BA10115

PPGx Sample Tube ID: PS22159

Sample Tube Volume: >=5

Sample Condition: Good

Subject Attributes:

Subject Number: 15678

Gender: M

Birthdate: 18-Sep-88

Ethnicity: Black

Comments:

Add Comments

Created: 10/9/99 20:03

Modified:

Place Samples

New

Delete

Modify

Save

Cancel

Close

Fig. 3

Sample Tracking

- ◆ Supports Multiple Container Classes
- ◆ Allows User Defined Container Geometries & Templates
- ◆ Maintains Sample & Container Location
- ◆ Permits Flexible Sample Loading & Rearrangement
- ◆ Tracks and Maintains Container & Sample Ownership

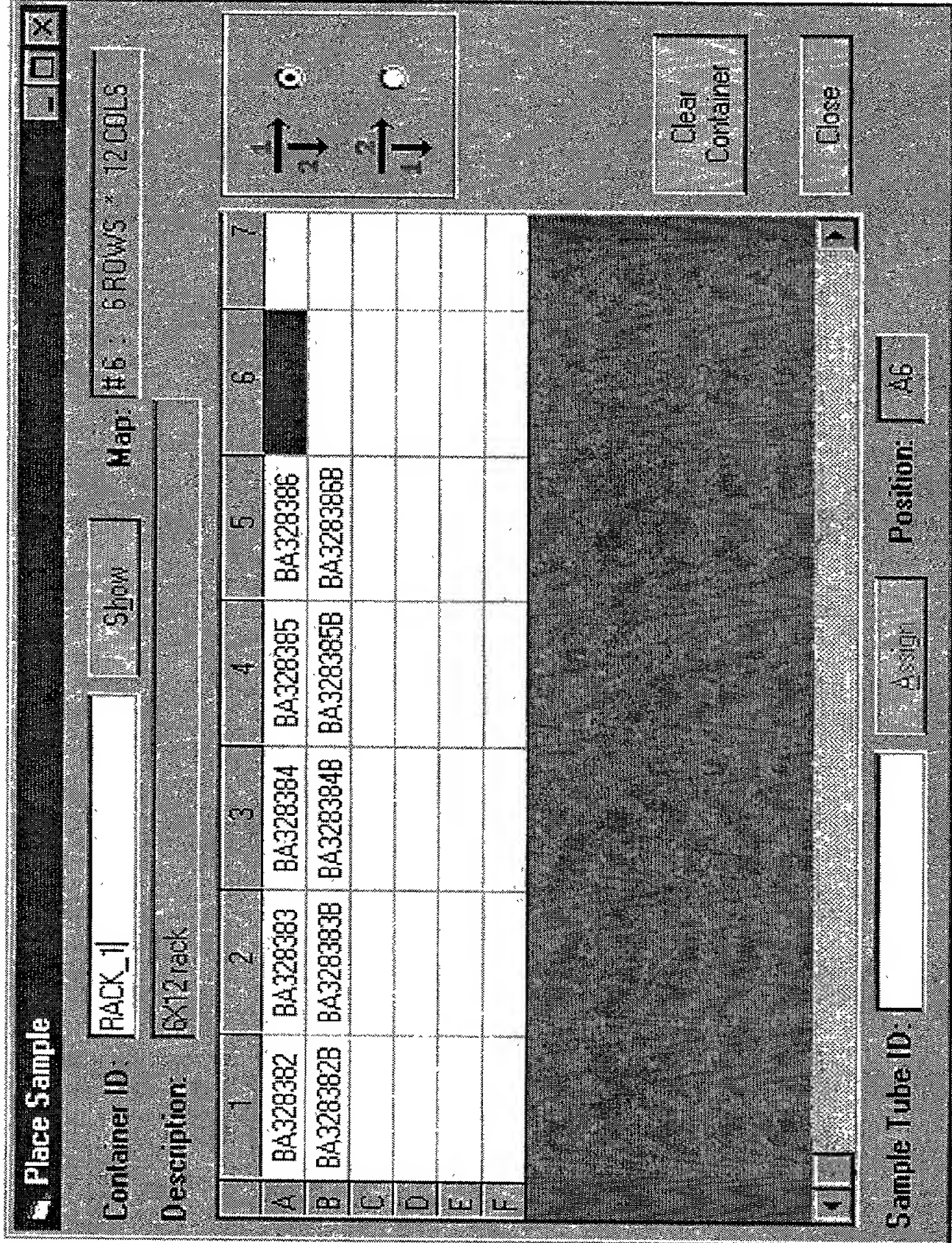


Fig. 4

- ◆ Sample Worklists
- ◆ Named Sample Collections
- ◆ Assignable to Lab Scientists
- ◆ Groups Samples for Common Lab Operations
 - Location
 - Check-in/Check-out
 - Lab Procedures

Worklists

Worklist Name	Assigned To	Created By	Created On	Mo
POC1005	DNALIMS	DNALIMS	10/5/99 13:54	DN
PS1 SAMPLES	DNALIMS	DNALIMS	10/6/99 08:02	DN
TODAY'S GENOTYPING	DNALIMS	DNALIMS	10/6/99 17:47	

Worklist Name: PS1 SAMPLES

Assigned To: DNALIMS

CONTAINERS

#R1

Sample Tube ID	Accession #	PPGx Study No	Location
S1	A1	PS1	Fr.1 Comp. Shelf Rack
S2	A2	PS1	Fr.1 Comp. Shelf Rack
S3	A3	PS1	Fr.1 Comp. Shelf Rack
S4	A4	PS1	Fr.1 Comp. Shelf Rack
S5	A5	PS1	Fr.1 Comp. Shelf Rack

Add Container

Add Sample

Add

Created

DNALIMS

10/6/99 08:02

Modified

DNALIMS

10/7/99 08:50

Modify

Cancel

Save

Save As

Delete

New

Check In

Check Out

Open Checklist

Print Worklist

Clear Worklist

Close

Fig. 5

Electronic Procedure Checklists

Automates Laboratory Process Tracking

- Supports Standard Operating Procedures
- Maintains Uniform Laboratory Processes
- Records Chain of Custody
- Tracks Repeat Operations

Procedure	Created By	Created On	Locked For M
DNA Isolation, 3 mL whole blood, Purgene Kit	DNALIMS	10/5/99 13:57	DNALIMS
CYP2D9*2 Ver.6	DNALIMS	10/5/99 14:19	
CYP2D9*2 Ver. 7	DNALIMS	10/5/99 14:39	
CYP2D9*2 Ver. 7	DNALIMS	10/5/99 14:40	
CYP2D9*3	DNALIMS	10/5/99 14:52	DNALIMS

Query

Delete Checklist

Print Checklist

NOTES	ALL SAMPLES	BA100100	BA100101	BA
Thaw frozen blood	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Gently mix sample	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Transfer 3 mL of blood to lysis tube	<input checked="" type="checkbox"/> DONE	<input checked="" type="checkbox"/> CA1111	<input checked="" type="checkbox"/> CA1112	
Add 9 mL of RBC lysis to RBC lysis tube	<input checked="" type="checkbox"/> DONE	<input checked="" type="checkbox"/> CA1111	<input checked="" type="checkbox"/> CA1112	
Mix and incubate 10 minutes at room tempera	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Centrifuge 10 minutes at 3000RPM		11009	11009	
Pour off supernatant into biohazardous waste	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Resuspend cell pellet by vortexing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Add 3 mL of Cell Lysis Solution	<input checked="" type="checkbox"/> DONE	<input checked="" type="checkbox"/> CA1111	<input checked="" type="checkbox"/> CA1112	

New Batch

Close

Created:	Created:
DNALIMS	10/5/99 13:57
DNALIMS	10/5/99 13:14

Locked:

Close

Fig. 6

PROCEDURES

Procedure

Status

SOP Number

SOP Version

DNA Isolation, 3 mL whole blood, Purgene Kit	APPROVED	GEN9709	C
2D6 Allele "A" Identification	APPROVED	CYP2D6A	A
SpectroMax DNA quantitation	APPROVED	MAX9802	A
CYP2C9*3	APPROVED	CYP2C9-3	A
CYP2C9*2 Ver. 7	APPROVED	CYP2C9-2	A
CYP2C9*2 Ver. 6	APPROVED	CYP2C9-2	A

Procedure Name:

2D6 Allele "A" Identification

Procedure Description:

Laboratory Protocol for Identification of CYP2D6 "A" Allele by RFLP-PCR

Print

Save As ...

Genes:

Alleles:

SOP Number:

CYP2D6A

SOP Version:

A

Status:

APPROVED

New

Save

Modify

Cancel

Delete

Close

Created

DNALIMS

10/4/99 12:02

Modified

DNALIMS

10/5/99 10:59

Fig. 7

Procedure Steps

- ◆ A Single Step in a Lab Procedure
- ◆ Multiple Types:
 - Transfer
 - Dilution
 - Concentration Adjustment
 - Sample Preparation
- ◆ Highly Customizable
- ◆ Plug-in Architecture to Add New Types
- ◆ Interfaces to Automation

Procedure Steps

Procedure: DNA Isolation, 3 mL whole blood, Purgene Kit

Print

Step	Step Input Type	Functional Type	Level
Thaw frozen blood	CheckBox		Batch
Gently mix sample	CheckBox		Batch
Transfer 3 mL of blood to lysis tube	Functional	Transfer	Batch
Add 9 mL of RBC lysis to RBC lysis tube	Functional	Reagent Addition	Batch
Mix and incubate 10 minutes at room temperature	CheckBox		Batch
Centrifuge 10 minutes at 3000RPM	Text		Batch
Pour off supernatant into biohazardous waste container	CheckBox		Batch
Resuspend cell pellet by vortexing	CheckBox		Batch
Add 3 mL of Cell Lysis Solution	Functional	Reagent Addition	Batch
Sample can be stored for 18 months at RT in Cell L	Informational		Batch
STOP POINT	Informational		Batch

Step: Add 9 mL of RBC lysis to RBC lysis tube

Step Level: ☐ Sample ☒ Batch

Step Type: ☒ Informational ☐ CheckBox ☐ Text

Reagent Addition

Volume	9000
To final volume	FALSE
Reagent name	RBC Lysis Sol
Reagent prefix	RL
Volume optional	
Wave scanning	TRUE
Lock parameters	TRUE

Created: DNA LIMS 10/5/99 09:00

Modified: DNA LIMS 9/30/99 14:42

Buttons: Save Sequence, New, Delete, Modify, Close

Fig. 8

Genotype Results

- ◆ Accommodates Values for Multiple Genes, Alleles & Assays
- ◆ Provides Master Review by Accession Number
- ◆ Supports Acceptance & Final Approval by Study Director
- ◆ Imports Results Electronically or Manually

Results

Study Protocol

Accession No.

Status

PS1

A3

OPEN

PS1

A4

OPEN

PS1

A5

OPEN

PS1

A6

OPEN

PS1

A7

OPEN

PS1

A8

OPEN

PS1

A9

OPEN

Study Protocol:

PS1

Sponsor:

C. Co., David Jones

Investigators:

Accession No:

A6

Status:

OPEN

Genotyping

DNA Purification

Chain Of Custody

Gene

Status

Interpretation

Exclude

Final GT

Entered By

Entered On

CYP2C9

COMPLETE

EXTENSIVE METABOLIZER

☐

wt/A

DNALIMS

10/6/99 6:48

Gene:

CYP2C9

Allele

Result

Batch

Procedure

Created By

Created On

Entered

m2

mt/wt

Batch

CYP2C9*2 Ver 7

DNALIMS

10/6/99 6:09:48 PM

DNALI

m2

mt/wt

Batch

CYP2C9*2 Ver 7

DNALIMS

10/6/99 6:09:48 PM

m2

mt/wt

FINAL RESULT

Fig. 9

Auditing

- ◆ Track Changes in Database
 - Study
 - Lab
- ◆ Procedures
 - Sample
 - Results
- ◆ Flexible Audit Reporting
- ◆ Chain of Custody by Accession

Audit Report									
Protocol Audit Trail									
STUDY_PROTOCOL	AUDIT_ID	PROTOCOL_ID	SPONSOR	STI	SPONSOR_PROTOCOL_TITLE	PPGX_STUDY_PPX_PROTOCOL_TITLE	CREATED_B		
	885	61	A1A		Evaluation of STUDY-1	X		DNALIMS	
	886	61	A1A		Evaluation of STUDY-1	X		DNALIMS	
	901	61	A1A		Evaluation of STUDY-1	X		DNALIMS	
	951	61	A1A		Evaluation of STUDY-1			Genomic DNA isolation and DNALIMS	
	963	61	A1A		Evaluation of			Genomic DNA isolation and DNALIMS	
	967	61	A1A		Evaluation of			Genomic DNA isolation and DNALIMS	
	980	61	PHO-001		Evaluation of			Genomic DNA isolation and DNALIMS	
	984	61	PHO-001		Evaluation of			Genomic DNA isolation and DNALIMS	
	971	61	PHO-001		Evaluation of			Genomic DNA isolation and DNALIMS	
	988	61	PHO-001		Evaluation of			Genomic DNA isolation and DNALIMS	
	1002	61	PHO-001		Evaluation of			Genomic DNA isolation and DNALIMS	
	1003	61	PHO-000		Evaluation of			Genomic DNA isolation and DNALIMS	
		61	PHO-001		Evaluation of			Genomic DNA isolation and DNALIMS	

Fig. 10

Reporting

- ◆ Multiple Report Types
 - Genotype Results
 - DNA Integrity
 - Purification Results
 - Sample Lists
 - Audit Trails
- ◆ Flexible Reporting Output Using Excel
- ◆ Customized Reporting Using 3rd Party Tools

DNA Purification Results										
Study:		Sponsor:				Representative:				
Test		Investigator(s):								
Study #: 999-xxx										
Sample #	Storage #	µg/ml	Protocol	Start Vol.	DNA Vol.	Yield	A260	A280	Subject Number	Initial Date of Birth
EA11111	0	0	Sample test	09/06/00	499	0	0	0	1 kal	5/31/66
EA11112	0	0	Sample test	02/19/00	48	0	0	0	2 lhb	8/2/67
EA11113	0	0	Sample test	09/06/00	248	0	0	0	3 lsc	5/22/66
EA11114	0	0	Sample test	09/06/00	248	0	0	0	4 jmm	4/11/74
EA11115	0	0	Sample test	09/06/00	248	0	0	0	5 tw	9/9/72
EA11117	0	0	Sample test	09/06/00	248	0	0	0	1 kal	5/31/66
EA11116	0	0	Sample test	09/06/00	98	0	0	0	2 lhb	8/2/67
EA11118	0	0	Sample test	09/06/00	248	0	0	0	3 lsc	5/22/66
EA11119	0	0	Sample test	09/06/00	582	0	0	0	4 jmm	4/11/74

Fig. 11